

REMARKS

The pending Office Action addresses claims 1-41, rejecting claims 20-25, 27-34, and 36-40. Claims 1-19, 26, 35, and 41 are withdrawn from consideration.

Amendments to the Claims

Applicants amend claims 20 and 37 to recite that the transmitter detects “acoustic signals” instead of “any acoustic signals.” No new matter has been added.

Claim 26 was inadvertently marked with the “withdrawn” status identifier in the Response to Restriction Requirement dated April 3, 2007 and in the Supplemental Response to Restriction Requirement dated April 18, 2007. As reflected in the listing of claims above, the proper identifier for claim 26 is “original.”

Applicants cancel non-elected claims 1-19 and 41. Applicants reserve the right to pursue these claims in a divisional application.

Claim Rejections Pursuant to 35 U.S.C. § 101

The Examiner rejects claims 20-25, 27-34, and 36-40 pursuant to 35 U.S.C. § 101, arguing that the claimed invention is directed to non-statutory subject matter. Applicants respectfully disagree.

Claim 20

Amended independent claim 20 recites an acoustic monitoring device for verifying the pressure setting of a valve mechanism in an implantable device having a plurality of adjustable valve settings. The acoustic monitoring device includes a transmitter configured to generate an energy field sufficient to effect movement of the valve mechanism of the implantable device and an acoustic sensor electronically coupled to the transmitter for detecting acoustic signals generated by the valve mechanism during an adjustment cycle.

The Examiner acknowledges that the device of claim 20 falls within an enumerated statutory category, but argues that the phrase “for detecting any acoustic signals” is an abstract idea and

therefore the claim is covered by a judicial exception to patentability. *Office Action* at 2-3. Merely including an abstract idea, however, is insufficient to render a claim unpatentable. *See Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Instead, the claim must be considered as a whole. *See id.* Contrary to the Examiner's unsupported blanket assertions, claim 20, when considered as a whole, produces a useful, concrete, and tangible result and therefore represents allowable subject matter.

i. *Claim 20 Produces a "Useful" Result*

To produce a "useful" result, a claim must be drawn to an invention that has specific, substantial, and credible utility. *See MPEP* §2106, 2107. The Examiner fails to set forth any evidence whatsoever that the claimed invention lacks a well-defined and particular benefit to the public (specific utility), is useless in its current form (substantial utility), or is wholly inoperative or incredible (credible utility). Instead, the Examiner merely states that "the claim does not actually solve a problem" and that "it does not appear to be specific as to how the problem is solved and, if solved, it is not specific as to the use of this solution." *Office Action* at 4.

Notwithstanding the Examiner's failure to establish a prima facie argument, Applicants submit that their invention has specific utility because it produces a well-defined and particular benefit to the public. As discussed in the specification at paragraph 0003, the claimed invention allows for "non-invasively monitoring the performance of implanted medical devices without requiring additional energy means such as x-ray, ultrasound, or telemetry." This is unmistakably a well-defined public benefit. Further, Applicants' invention has substantial utility because it is useful to the public as disclosed in its current form -- no further research is required for the invention to prove useful. Rather, the device of claim 20 can be used as it stands today to verify the pressure setting of a valve mechanism in an implanted device. Lastly, the device of claim 20 has credible utility because it successfully performs its intended purpose.

ii. *Claim 20 Produces a "Concrete" Result*

To satisfy the "concrete" requirement, an invention must produce a "substantially repeatable" result. *See MPEP* §2106. The Examiner argues that the device of claim 20 does not produce a concrete result because "the result can not be substantially repeatable and the process can not substantially produce the same result again." *Office Action* at 4-5. First, claim 20 is directed to a

device, not a process as suggested by the Examiner. Second, the Examiner's argument is simply a restatement of the "concrete" test and fails to offer even a shred of evidence that the result of claim 20 is not repeatable.

To the contrary, the device of claim 20 is capable of verifying the pressure setting of a valve mechanism in an implantable device as many times as the user wishes. In fact, as explained in the specification at paragraph 0100, "[t]he clinician may repeat the adjustment process until satisfied." Since the claimed device can repeatedly verify the pressure setting of a valve mechanism, it produces a "concrete" result.

iii. *Claim 20 Produces a "Tangible" Result*

If a claim includes a judicial exception, it must recite a practical application of that exception that produces a real-world result in order to satisfy the "tangible" requirement. *See MPEP* §2106. The Examiner states on page 4 of the Office Action that:

Regarding the tangible result requirement, the claim clearly does not provide a practical application. The problem, even if solved, is not practically applied to produce a real world result. For example, once the problem is solved, how is this then applied?

Again, no evidence is offered in support of this argument by the Examiner.

Claim 20, by its express terms, recites a practical application of "detecting acoustic signals." Specifically, "verifying the pressure setting of a valve mechanism in an implantable device." There is no question that non-invasively monitoring the status of an implanted device is a "real-world" result and therefore the device of claim 20 satisfies the "tangible result" requirement.

Accordingly, claim 20 produces a useful, concrete, and tangible result and therefore represents allowable subject matter. Claims 21-25, 27-34, and 36 are allowable at least because they depend from an allowable base claim.

Claim 37

Amended independent claim 37 recites an acoustic monitoring system for verifying the pressure setting of a valve mechanism in an implantable device having a plurality of adjustable valve

settings. The system includes a device for adjusting the opening pressure of the valve mechanism and a transmitter configured to generate an energy field sufficient to cause movement of the valve mechanism. The system also includes an acoustic sensor electrically coupled to the transmitter for detecting acoustic signals generated by the valve mechanism during an adjustment cycle, wherein the transmitter communicates the detected acoustic signal to the device for analysis.

For the same reasons discussed above with respect to claim 20, claim 37 produces a useful, concrete, and tangible result and therefore represents allowable subject matter. Claims 38-40 are allowable at least because they depend from an allowable base claim.

Claim Rejection Pursuant to 35 U.S.C. § 112

The Examiner rejects claims 20-25, 27-34, and 36-40 pursuant to 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. The Examiner asserts that in claims 20 and 37, it is unclear how the energy field sufficient to effect movement of the valve mechanism is generated. *Office Action* at 6. Applicants respectfully disagree.

Claims 20 and 37 are sufficiently definite to inform the public of the boundaries of the claimed invention. According to MPEP §2173.02, “[t]he test for definiteness under 35 U.S.C. §112, second paragraph, is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’ *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.* 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir., 1986).” More recently, the Federal Circuit has noted that: “[o]nly after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.* 309 F.3d 774, 780 (Fed. Cir. 2002); *see also Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (finding that “only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite”).

The manner in which the energy field of claims 20 and 37 is generated would be easily understood by a skilled artisan when the claims are read in light of the specification and therefore the claims are definite. Paragraphs 0007 and 0039 of the specification discuss methods for generating

such a field. In addition, Paragraphs 0012, 0014, 0016, 0039, 0041, 0043, 0047, 0051, 0053, 0070-0073, 0084, 0086, 0091, and 0097 discuss various aspects of generating the energy field in the claimed invention. Accordingly, claims 20 and 37 are adequately enabled by the specification and fulfill the definiteness requirement of 35 U.S.C. §112, second paragraph. Claims 21-25, 27-34, 36, and 38-40 are allowable at least because they depend from allowable base claims.

Double Patenting

The Examiner rejects claims 20-25, 27-34, and 36-40 pursuant to nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,685,638 of Taylor et al. Applicants submit herewith a Terminal Disclaimer, the filing of which should obviate this rejection.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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/William C. Geary III/
William C. Geary III, Reg. No. 31,359
Attorney for Applicant(s)

Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2766
Fax: (617)310-9766